46. (Amended) An isolated and purified fragment of the *P. haemolytica* genome, wherein said fragment modulates the expression of TbpA, said fragment consisting of a nucleotide sequence from about 10 to 200 bases in length which is 5' to:

(a) the open reading frame depicted in SEQ ID NO:1 or

(b) an open reading frame encoding a TbpA polypeptide of *P. haemolytica,* said open reading frame comprising a nucleic acid sequence that hybridizes under stringent conditions to the complement of the sequence as set forth in SEQ ID NO:1, wherein said stringent conditions include a post-hybridization wash of 2 x SSC (sodium chloride/sodium citrate) at 50°C.

REMARKS

Claims 5-7, 9, 11, 13, 15-19, 21-27 and 29-48 were pending in the subject application. Claims 5-7, 9, 11, 13, 15-19, 21-27, 29, 42 and 48 have been withdrawn from examination as allegedly being directed to a non-elected invention. Claims 30-41 and 43-47 have been examined on the merits. By submission of this paper, claims 30, 40, 43 and 46 have been amended.

Claim 30 has been amended to specify that the claimed polynucleotide encodes a polypeptide that is a TbpA of *P. haemolytica*, or is the full complement of a polynucleotide that encodes a polypeptide that is a TbpA of *P. haemolytica*. Support for this amendment can be found in the specification, for example at page 8, lines 25-26, and at page 9, lines 3-8. Claim 40 has been amended to insert the word "cell" after "host" and

to replace the term "protein" with the term "polypeptide," in order to make parts (a) and (b) of this claim consistent with the preamble. Claim 43 has been amended to correct a typographical error. Claim 46 has been amended to better define the recited open reading frame and is supported in the specification, for example, at page 9, lines 9-10 and lines 25-31. No new matter is added by the amendments. Applicants submit that the amendments put the application in condition for allowance and, therefore, respectfully request that the amendments be entered into the application.

Objection to Claim

Claim 43 has been objected to for minor informalities. As the Examiner can ascertain, claim 43 has been amended to correct a typographical error and to obviate the objection. Applicants respectfully request the withdrawal of the objection.

Rejection under 35 U.S.C §112

Claim 46 stands rejected under 35 U.S.C. §112 based on the Examiner's assertion that the claim is indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Applicants respectfully traverse this rejection. The Examiner has asserted that the term "degenerate variant" is vague and indefinite. Applicants respectfully point out that nucleic acid molecules encoding a protein having the activity of a TbpA, but which differ from the sequence set forth in SEQ ID NO:1 due to the degeneracy of the genetic code are described in the specification (for example, at page 9, lines 32-38). The Applicants submit that it is well known in the art that variants of a particular sequence frequently occur due to the degeneracy of the genetic code. Such variants contain one or

more nucleotide changes but are understood to encode proteins with the same activity. Applicants submit that a worker skilled in the art would understand what is meant by the term "degenerate variant" and that this term, therefore, is not vague or indefinite.

Solely to expedite prosecution of the claims, however, Applicants have amended claim 46 to remove the term "degenerate variant," and to define the open reading frame as having a nucleic acid sequence that hybridizes under defined stringent conditions to the complement of the sequence as set forth in SEQ ID NO:1. This amendment is fully supported by the specification as indicated in the above discussion of the amendments. Applicants, therefore, respectfully request that the rejection of claim 46 under 35 U.S.C. §112 be withdrawn.

Rejection under 35 U.S.C. § 102(e)

Claims 30, 31, 34-40, 46 and 47 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,922,562. The Examiner has asserted the aforementioned U.S. patent discloses a degenerate variant polynucleotide which hybridizes under stringent conditions to a polynucleotide which is complementary to the polynucleotide of (a), (b) or (c), under the defined stringency conditions and vectors and host cells containing said vectors used in methods to produce the disclosed polypeptide.

Applicants respectfully traverse the Examiner's rejection. Applicants respectfully remind the Examiner that in order for a reference to anticipate the claimed invention, the reference must contain all of the material elements of the claimed invention. In re Marshall 577 F.2d 301, 3 U.S.P.Q. 344 (C.C.P.A. 1978). Claims 34 and 35 are directed to a polynucleotide of claim 30 that comprises the sequence as set forth in

SEQ ID NO:1 from nucleotide 1 to nucleotide 2790 and from nucleotide 85 to nucleotide 2790, respectfully. Claim 46 is directed to an isolated and purified fragment of the *P. haemolytica* genome which modulates the expression of TbpA. U.S. Patent No. 5,922,562 does not disclose polynucleotides comprising SEQ ID NO:1, or fragments of the *P. haemolytica* genome which modulate expression of TbpA. Applicants submit that claims 34, 35 and 46 are not, therefore, anticipated by U.S. Patent No. 5,922,562.

Furthermore, as shown in the database sheet provided by the Examiner, Sequence 3 of U.S. Patent No. 5,922,562 shows only 1354 matches over a 2619 nucleotide region with the nucleic acid sequence as set forth in SEQ ID NO:1 of the present invention (*i.e.* an overall identity for this region of 51.7%) and, additionally contains 15 gaps in the alignment, one of which is 87 nucleotides in length. Applicants submit that one skilled in the art would not predict that the nucleic acid sequence of Sequence 3 in U.S. Patent No. 5,922,562 would hybridize to a polynucleotide which is complementary to the polynucleotide of (a), (b) or (c) as defined in claim 30 of the present invention under the defined high stringency conditions.

Solely to expedite prosecution of these claims, however, Applicants have amended claim 30 to specify that the claimed polynucleotide either encodes a polypeptide that is a TbpA of *P. haemolytica,* or is the full complement of a polynucleotide that encodes a polypeptide that is a TbpA of *P. haemolytica*. Applicants, therefore, respectfully request that this 35 U.S.C. §102(e) rejection be withdrawn.

Allowable Subject-Matter

Applicants acknowledge, with appreciation, that the Examiner has indicated that claims 32 and 41-45 would be allowable if re-written in independent form including all of the limitations of the base claim and any intervening claims. Applicants submit that amended claim 30, which is the base claim for claims 32 and 41-45, is now in condition for allowance and that claims 32 and 41-45, therefore, also meet with these requirements.

A petition for extension of time to respond to the October 23, 2001 Office Action and the requisite extension of time fee are enclosed herewith. Applicants do not believe that any additional fee is due. If any such fee is due, or if any overpayment has been made, the Commissioner is authorized to change any such fee or credit any overpayment to our Deposit Account No. 02-4377.

Respectfully submitted,

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MARKED UP VERSION OF THE CLAIMS TO INDICATE CHANGES MADE

IN THE CLAIMS

Please amend claims 30, 40, 43, and 46 currently on file, as follows:

30. (Amended) An isolated and purified first polynucleotide, or the full complement of said first polynucleotide, wherein said first polynucleotide encodes a polypeptide that is a TbpA of *P. haemolytica* and [which] hybridizes under stringent conditions to the complement of a second polynucleotide, wherein said second polynucleotide is [a member] selected from the group consisting of:

(a) a polynucleotide encoding a [TbpA] polypeptide [of *P. haemolytica*] comprising an amino acid sequence as set forth in SEQ ID NO:2;

(b) a polynucleotide encoding a [TbpA] polypeptide [of *P. haemolytica*] comprising amino acid 1 to amino acid 930 as set forth in SEQ ID NO:2; and

(c) a polynucleotide encoding a [TbpA] polypeptide [of *P. haemolytica*] comprising amino acid 29 to amino acid 930 as set forth in SEQ ID NO:2; [and

(d) a polynucleotide which is complementary to the polynucleotide of (a), (b) or (c),]

wherein said stringent conditions include a post hybridization wash of 2X SSC (sodium chloride/sodium citrate) at 50EC.

40. (Amended) A method for producing a polypeptide in a host cell comprising the steps of:

(a) incubating a host cell containing a heterologous nucleic acid molecule whose nucleotide sequence comprises the sequence of the isolated polynucleotide of claim 30, under conditions where said heterologous nucleic acid molecule is expressed to produce said polypeptide [protein] and

(d) isolating said polypeptide [protein].

43. (Amended) An isolated and purified nucleic acid molecule comprising the polynucleotide of claim 30,[.] wherein said nucleic acid molecule is produced by a process comprising the steps of:

(a) screening a genomic DNA library using as a probe a target sequence defined by the SEQ ID NO:1, or fragments thereof;

(b) identifying members of said library which contain sequences that hybridize to said target sequence; and

(e) isolating an intact coding sequence from one or more of said members identified in step (b).

46 47. (Amended) An isolated and purified fragment of the *P. haemolytica* genome, wherein said fragment modulates the expression of TbpA, said fragment consisting of a nucleotide sequence from about 10 to 200 bases in length which is 5' to:

(c) the open reading frame depicted in SEQ ID NO:1 or

(d) an open reading frame encoding a TbpA polypeptide of *P. haemolytica,* said open reading frame comprising a nucleic acid sequence that

hybridizes under stringent conditions to the complement of the sequence as set forth in SEQ ID NO:1, wherein said stringent conditions include a post-hybridization wash of 2 x SSC (sodium chloride/sodium citrate) at 50°C [a degenerate variant of said open reading frame].